K123118

Sybron Dental Specialties

MAR 2 6 2013

510K SUMMARY

Submitter:

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Wendy Garman - Contact Person

Date Summary Prepared: March 2013

- Trade name – ***Insignia Digicast***
- Common name –Digital Study Model
- Classification name – Orthodontic Plastic Bracket (21 CFR§872.5470)
- Product Codes – DYW (Orthodontic Plastic Bracket)
  EJF (Orthodontic Metal Bracket)
  NJM (Orthodontic Ceramic Bracket)

Device for Which Substantial Equivalence is Claimed:

- Lava Digital Models, Marketed by 3M Unitek
  Class I Exempt
  Product Code: LMD (21CFR§892.2020)

- OrthoCAD iQ, Marketed by Cadent, Inc.
  Class II
  Study model described within K082207
  Product Code: DYW (Orthodontic Plastic Bracket, 21CFR§872.5470)
  EJF (Orthodontic Metal Bracket, 21CFR§872.5410)
  NJM (Orthodontic Ceramic Bracket, 21CFR§872.5470)

Summary

Device Description

Insignia Digicast is a software product and service that creates digital models of patients' teeth, which are used primarily to record the status of a patients' dentition prior to treatment.

Clinicians may also use the digital model to support their diagnosis. The ***Insignia Digicast*** system scans a traditional impression, processes the scan, and electronically delivers a digital study model to the dental professional.

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The dental professional may view, measure, and analyze the study model using the ***Insignia Digicast*** three dimensional viewer software. The main analysis tools include TJ Moyers, Bolton analyses, ABO scoring, and Arch and Overbite/Overjet measurements.

There are no accessories or patient contacting components of ***Insignia Digicast.***

Indications for Use of the Device

Insignia Digicast is a computer aided system intended for use as an aid in orthodontic diagnostics for use by dental professionals trained in orthodontic treatment including radiographic analyses and diagnostics.

Technological Characteristics Compared to Predicate

Features	***Insignia Digicast***	*OrthoCAD iQ*	*Lava Digital Model*
Indications for Use	***Insignia Digicast*** is a computer aided system intended for use as an aid in orthodontic diagnostics for use by dental professionals trained in orthodontic treatment including radiographic analyses and diagnostics.	*Ortho CAD iQ* is a computer-guided system intended for use as an aid in orthodontic treatment planning for use by dental professionals trained in orthodontic treatment including radiographic analyses and treatment planning. *OrthoCAD iQ* is intended for use with commercially-available brackets and wires that apply continuous gentle force to reposition the teeth. It also uses indirect bonding trays to affix the brackets in position.	Lava Digital Models is a software product that allows clinicians to display and interact with digital study models for patient consultations. Lava Digital Models scans a traditional impression, processes the scan and electronically delivers the digital study model to the dental professional. The dental professional may view, measure and analyze the digital study model.

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Features (cont.)	***Insignia Digicast***	OrthoCAD iQ	Lava Digital Model
Mode of Use	The ***Insignia Digicast*** system scans a traditional impression, processes the scan, and electronically delivers a digital study model to the dental professional.	The OrthoCAD iQ system scans a traditional impression, processes the scan, and electronically delivers a digital study model to the dental professional.	The Lava Digital Models system scans a traditional impression, processes the scan, and electronically delivers a digital study model to the dental professional.
Manufacturing Method	A dental professional takes an alginate or PVS impression of the patient's teeth. The impression is then scanned and converted into a digital model. This model is then uploaded for use by the practitioner.	A dental professional takes an alginate or PVS impression of the patient's teeth The impression is then scanned and converted into a digital model. This model is then uploaded for use by the practitioner.	A dental professional takes an alginate or PVS impression of the patient's teeth The impression is then scanned and converted into a digital model. This model is then uploaded for use by the practitioner.
Analyses Available	The following analyses are available for use by the dental practitioner: Bolton Analysis, Tanaka-Johnston/Moyers Analysis, Space Analysis, and ABO Discrepancy Index Scoring.	The following analyses are available for use by the dental practitioner: Bolton Analysis, Tanaka-Johnston/Moyers Analysis, Space Analysis, and ABO Discrepancy Index Scoring.	Instantly obtain point-to-point measurements with automatic calculations and auto-sums (Bolton analysis, arch length, overbite and overjet).

Non-Clinical Performance Data

This 510(k) submission includes data from bench testing used to evaluate the performance characteristics of ***Insignia Digicast*** compared to the predicate device, OrthoCAD iQ. The characteristics evaluated include, but were not limited to, teeth width, space, T-J Moyers, Bolton, Arch and Overbite/Overjet.

The ***Insignia Digicast*** software has been successfully validated to confirm the performance of the device.

Clinical Testing

Clinical testing has not been conducted on this product.

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Conclusion

Based upon the similar technological/performance characteristics as compared to the predicate devices, and successful validation of the ***Insignia Digicast*** software, the performance of the ***Insignia Digicast*** is deemed to be substantially equivalent to the OrthoCAD iQ and Lava Digital Models. Additionally, there are no functional differences between the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 26, 2013

Ormco Corporation
C/O Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties
1717 West Collins Avenue
ORANGE CA 92867

Re: K123118
Trade/Device Name: INSIGNIA DIGICAST
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW, NJM, EJF
Dated: February 22, 2013
Received: February 25, 2013

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: *INSIGNIA DIGICAST*

Indications For Use:

Insignia Digicast is a computer aided system intended for use as an aid in orthodontic diagnostics for use by dental professionals trained in orthodontic treatment including radiographic analyses and diagnostics.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.03.26 11:56:21 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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